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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,605	02/04/2005	Kosaburo Wakamatsu	04676.0161	1449
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KAROL, JODY LYNN	
			ART UNIT	PAPER NUMBER
			4133	
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			11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,605

Applicant(s)

WAKAMATSU ET AL.

Examiner

Jody L. Karol

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/4/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-13, and 15-20 is/are rejected.
- 7) ☒ Claim(s) 1 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/16/2005 and 10/27/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/JP03/09783 International Filing Date: 8/1/2003, which claims priority to JP 2002-228368. Claims 2, 4, and 14 have been cancelled and claims 1, 12, and 18-20 have been amended as per applicant's PCT Article 34 amendment dated 2/4/2005. Accordingly, claims 1, 3, 5-13, and 15-20 are pending and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statements (IDS) filed on 5/16/2005 and 10/27/2005 in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on Application No. 2002-228368 filed with the European Patent Office on 8/6/2002.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. The disclosure is objected to because of the following informalities: extraneous spacing is present throughout the specification.

Appropriate correction is required.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

6. Claims 1 and 20 are objected to because of the following informalities: the term "salt" should be the plural "salts." Currently the claims read that L-ascorbyl phosphate salt and cyclic adenosine 3',5'-adenosine monophosphate salt are the only possible salts in the composition. However, the dependent claims (see claims 3 and 5 for example) indicate that other salts such as ascorbic acid 2-glucoside salt may be present. Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 3, and 5-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6 of copending Application No. 11/722965.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims sets are directed to composition comprising an adenosine monophosphate and an ascorbic acid derivative, such as ascorbic-2-glucoside. There are additional components present in the compositions of the copending claims. However, the term "comprising" is interpreted as broad and open-ended, and other components not mentioned may be present in the compositions of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-13 and 15-17 are directed to a method of potentiating the anti-aging effect of ascorbic acid, a derivative thereof, or salt thereof. However, the claims do not recite any positive steps for carrying out the claimed method. The claims merely recite "using" certain components. Where the anti-aging action occurs is not specified (i.e. in a human in need thereof), and how the components are used is not specified (i.e. applying to the skin). Since the "methods" of claims 12-13 and 15-17 have no steps, they each read on a product.

Claims 19 provides for "the use" of an ascorbic acid derivative and an adenosine monophosphate for the manufacture of an anti-aging composition. Claim 20 provides for "the use" of a purine nucleic acid-related substance for potentiating the action of an ascorbic acid derivative. However, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

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35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 10-11 are rejected under 35 U.S.C. 102(a) as being anticipated by www.nuinternational.co.jp/seibun.html+AMP published online on 6/6/2003. The Applicant's explanation of the relevance of the publication on the IDS submitted on 5/16/2005 is being used as the English translation of this document.

Claims 1 and 10-11 are directed to compositions comprising at least one member selected from the group consisting of ascorbic acid 2-glucoside, ascorbyl tetraisoalmitate, L-ascorbyl phosphate, and a salt thereof; and at least one purine nucleic acid-related substance selected from the group consisting of adenosine 2'-monophosphate, adenosine 3'-monophosphate, adenosine 5'-monophosphate, cyclic adenosine 3', 5'-monophosphate, and a salt thereof. The term comprising is interpreted as broad and open-ended. Claims 10-11 list intended uses for the composition, and are not considered to further limit claim 1.

The Applicant states that the website describes a refreshing gel comprising Mg ascorbyl phosphate and AMP (adenosine monophosphate). The ascorbyl phosphate is not specified as D or L and is therefore considered a mixture of D and L isomers. The placing of the phosphate group of adenosine monophosphate (AMP) is not specified, however, a phosphate group can only attach on an adenosine molecule where there is a hydroxyl group. Hydroxyl groups are present on adenosine at the 2', 3' and 5' positions, so the AMP must be adenosine 2'-monophosphate, adenosine 3'-monophosphate, adenosine 5'-monophosphate, or mixtures thereof. Therefore, the limitations of claims 1 and 10-11 are met.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1). US 6,946,436 B2 is used as the English equivalent of Wakamatsu et al. (WO 2002/41853).

Claims 1, 3, and 5-11 are directed to compositing comprising an ascorbic acid derivative and an adenosine monophosphate (AMP) as described above. Claim 5-6 specify that the AMP is adenosine 5'-monophosphate or salt thereof and claims 3 and 6 specify that the ascorbic acid derivative is ascorbic acid 2-glucoside or salt thereof. Claims 7-9 further limit the amount of the components.

Wakamatsu et al. teaches an O/W emulsion composition comprising an electrolyte, where the preferred electrolytes are adenosine monophosphate, cyclic adenosine monophosphate, salts thereof, ascorbic acid, and derivatives thereof (see column 7, lines 9-36 and claims 3-4). The adenylic acid derivatives (i.e. adenosine monophosphate) are known to exhibit moisturizing and anti-aging effects when applied to the skin (see column 7, lines 45-54 and column 16, lines 1-15). Wakamatsu et al. further teaches that the electrolytes can be used alone or in combination of two or more species (see column 7, lines 39-40) and the amount of electrolytes contained in the composition is not limited, but is at least 0.1% by weight, and preferably 0.5 to 7% by weight as claimed in the instant claims 7-9 (see column 7, line 66 to column 8, line 5

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and claims 12-14). Wakamatsu et al. teaches specific examples where adenosine monophosphate disodium is present in the composition in 1.5%, 3.0% and 6.0% by weight (see Table 1, examples 1-4) and where sodium L-ascorbic acid phosphate ester (L-ascorbyl phosphate salt) is present in the composition in 2.0 and 3.0% by weight (see Table 1, examples 5-6). As explained above, adenosine monophosphate (AMP) is adenosine 2'-monophosphate, adenosine 3'-monophosphate, adenosine 5'-monophosphate, or mixtures thereof.

Wakamatsu et al. does not teach any specific examples where the AMP and ascorbic acid derivative are present in the same composition. Wakamatsu et al. also does not teach the function of ascorbic acid derivatives or ascorbic acid 2-glucoside as an ascorbic acid derivative.

Castiel et al. teaches Vitamin C derivatives more stable than ascorbic acid itself and which combat or prevent intrinsic aging of the skin (see abstract). One of the preferred ascorbic acid derivatives is a 2-O- α -D-glucopyranosyl of ascorbic acid, also known as ascorbic acid 2-glucoside (see page 2, sections 32, 35, and 41). Castiel et al. further teaches the compositions contain 0.001 to 10% by weight of ascorbic acid derivatives (see page 2, section 42), and gives an example of composition with ascorbic acid 2-glucoside present in 0.1% by weight of the composition (see page 4, section 77).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine an adenosine monophosphate as taught by Wakamatsu et al. with the ascorbic acid derivatives of Wakamatsu et al. and Castiel et al. to formulate a composition with anti-aging action, since adenosine monophosphate derivatives and

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ascorbic acid derivatives are both used individually in the art for the same purpose, namely to keep skin from aging. It is obvious to one of ordinary skill in the art to combine components taught individually in the art as having the same purpose to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980).

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 274-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK



JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER